

Tennessee's Health

Guidelines For Growth



**Criteria and Standards
for
Certificate of Need
2000 Edition**

**Prepared by the
Health Planning Commission**

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PREFACE

The Tennessee Certificate of Need Program is administered by the Health Facilities Commission under the authority of Tennessee Code Annotated Title 68, Chapter 11, Part 1, the Tennessee Health Planning and Resource Development Act of 1987. The Department of Health, the Department of Mental Health and Developmental Disabilities, and the Division of Mental Retardation Services provides technical support for the Health Facilities Commission. This will be in the form of a written review and analysis of the project. It will compare these guidelines with the applicant's projections and the existing data in the service area.

The criteria and standards contained in this manual are used by certificate of need (CON) applicants and the reviewing authority to generate baseline information during the review process. The information is then used as the basis for decisions concerning certificate of need proposals.

Certificate of Need applications are reviewed by the Health Facilities Commission in accordance with three major criteria: need, economic feasibility, and contribution to the orderly development of adequate and effective health care. The following criteria and standards do not supersede the code section in any way and are meant to provide additional guidance to assist the Commission in its review of CON applications.

In this document, the user will find specific criteria and standards concerning the need for the facility or service in question. Please note that generic sets of criteria and standards concerning economic feasibility and the contribution to the orderly development of health care are listed on pages 8 and 9.

Types of facilities and services referred to in these guidelines were selected from appropriate sections of the Tennessee Code Annotated, Rules of the Health Facilities Commission, Department of Health, Department of Mental Health and Developmental Disabilities, Division of Mental Retardation Services, and other recognized professional health organization publications.

Prospective applicants are encouraged to contact the Health Facilities Commission staff concerning the review process before preparing an application. The staff is available to provide advice or other relevant information.

Correspondence and telephone calls should be directed to the:

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Nashville, TN 37219
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During the development of this document, the Commission received advice from a number of State agencies including the Department of Mental Health and Developmental Disabilities, Division of Mental Retardation Services, and the Department of Health (Bureau of Policy Planning and Assessment, Bureau of Alcohol and Drug Abuse Services, and the Division of Health Care Facilities - Office of Health Licensure and Regulation). Other agencies involved were the Tennessee Medical Association, Tennessee Hospice Association, Tennessee Association for Home Care, and the Tennessee Perinatal Advisory Committee. The Commission wishes to express appreciation for all assistance received.

HEALTH PLANNING COMMISSION PHILOSOPHY

The following are philosophic positions and guidelines of the Health Planning Commission to be considered by the Health Facilities Commission or other commissions when reviewing applications for certificates of need.

1. The Health Planning Commission (HPC) supports a philosophy that directs the delivery of health care services to the most medically appropriate, least intensive (restrictive) and most cost-effective health care settings.
2. The HPC recognizes all institutions as equal regardless of ownership, i.e., for profit, not for profit, government, etc., but strongly favors those institutions that provide services to the elderly, categorically needy, and indigent patients. When applying any specific formula, the elderly, categorically needy, and/or indigent patients not served by the facility will be removed from that formula. For example, those providers who do not provide services to TennCare patients will subtract the appropriate TennCare population from the total population to be served before applying the formula. This pertains to all types of providers seeking a certificate of need.
3. The HPC supports the position that every citizen, regardless of ability to pay, should have access to basic health care services, i.e., those services provided in a clinic setting or secondary hospital setting (basic inpatient care, obstetrics, primary surgical services, and emergency care).
4. The HPC feels that preference should be given to patient accessibility, availability, and affordability needs when making a certificate of need determination of establishment, relocation, replacement, or discontinuation of health care institutions or services.

**RULES
OF
THE TENNESSEE HEALTH FACILITIES COMMISSION
CHAPTER 0720-4
CERTIFICATE OF NEED PROGRAM-GENERAL CRITERIA
TABLE OF CONTENTS**

0720-4-.01 General Criteria for Certification of Need

0720-4-.01 GENERAL CRITERIA FOR CERTIFICATE OF NEED. The Commission will consider the following general criteria in determining whether an application for a certificate of need should be granted:

- (1) Need. The health care needed in the area to be served may be evaluated upon the following factors:
 - (a) The relationship of the proposal to any existing applicable plans;
 - (b) The population served by the proposal;
 - (c) The existing or certified services or institutions in the area;
 - (d) The reasonableness of the service area;
 - (e) The special needs of the service area population, including the accessibility to consumers, particularly women, racial and ethnic minorities, and low-income groups;
 - (f) Comparison of utilization/occupancy trends and services offered by other area providers;
 - (g) The extent to which Medicare, Medicaid, and medically indigent patients will be served by the project.
- (2) Economic Factors. The probability that the proposal can be economically accomplished and maintained may be evaluated upon the following factors:
 - (a) Whether adequate funds are available to the applicant to complete the project;
 - (b) The reasonableness of the proposed project costs;
 - (c) Anticipated revenue from the proposed project and the impact on existing patient charges;
 - (d) Participation in state/federal revenue programs;

(Rule 0720-4-.01 continued)

- (e) Alternatives considered;
 - (f) The availability of less costly or more effective alternative methods of providing the benefits intended by the proposal.
- (3) Contribution to the Orderly Development of Adequate and Effective Healthcare Facilities and/or Services. The contribution which the proposed project will make to the orderly development of an adequate and effective health care system may be evaluated upon the following factors:
- (a) The relationship of the proposal to the existing health care system (for example: transfer agreements, contractual agreements for health services, affiliation of the project with health professional schools);
 - (b) The positive or negative effects attributed to duplication or competition;
 - (c) The availability and accessibility of human resources required by the proposal, including consumers and related providers;
 - (d) The quality of the proposed project in relation to applicable governmental or professional standards.
- (4) Applications for Change of Site. When considering a certificate of need application which is limited to a request for a change of site for a proposed new health care institution, the Commission may consider, in addition to the foregoing factors, the following factors:
- (a) *Need.* The applicant should show the proposed new site will serve the health care needs in the area to be served at least as well as the original site. The applicant should show that there is some significant legal, financial, or practical need to change the proposed new site.
 - (b) *Economic factors.* The applicant should show that the proposed new site would be at least as economically beneficial to the population to be served as the original site.
 - (c) *Contribution to the orderly development of health care facilities and/or services.* The applicant should address any potential delays that would be caused by the proposed change of site, and show that any such delays are outweighed by the benefit that will be gained from the change of site by the population to be served.

Authority: T.C.A. §§68-11-105(2) and 68-11-108(b).

ECONOMIC FACTORS AND CONTRIBUTIONS TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

(Generic Sets of Criteria Which May Be Applied
to all Applications for Certificate of Need)

A. ECONOMIC FACTORS

1. Immediate financial feasibility:

- a. The cost per square foot of new construction should be reasonable in relation to similar facilities in the state;
- b. The financing mechanism should be structured to assure that funds to develop the facility will be available on reasonable terms;
- c. The business plans for the facility will take into consideration the special needs of the service area population, including the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. The HFC will take specific note of these considerations when making their certificate of need determinations;
- d. The proposed charges should be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas;
- e. Staff salaries should be reasonable in comparison with prevailing wage patterns in the area.

2. Long term financial feasibility:

- a. The projected utilization rates should be sufficient to maintain cost-effectiveness;
- b. The projected cash flow should ensure financial viability within two years and evidence should be shown that sufficient cash flow is available until that point is reached so as not to threaten the long term financial viability of the facility.

3. Consideration of more cost-effective alternatives:

- a. The existence of superior alternatives in terms of costs, efficiency, and efficacy should be identified. If development of such alternatives is not practicable, the applicant should justify why not;
- b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.

B. CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE

1. Availability of appropriate professional staff:

- a. All licensing certifications as required by the State of Tennessee for professional staff shall be met. These include, without limitation, regulations concerning physician credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.
- b. The applicant should document the availability of adequate professional staff, as per licensing requirements, to deliver all designated services in the proposal.

2. Licensure, Accreditation, and Certification:

- a. All licensed health care facilities and services shall comply with licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, and the Division of Mental Retardation Services.
- b. An existing provider must document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction.
- c. It will be deemed to be a positive factor if the applicant seeks certification to participate in both the Medicare and TennCare programs, so as to afford access for those populations.

3. Consideration of Alternatives:

The applicant's alternatives to the proposed project should indicate logical reasons as to why they were adopted or rejected.

4. Effect on Existing Providers:

The applicant should describe the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

5. Data Collection:

The applicant should state in the proposal that it will, if approved, provide the Tennessee Health Facilities Commission and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

SECTION I

NURSING HOME AND HOSPITAL FACILITIES

NURSING HOME SERVICES

Public Chapter No. 1112, Senate Bill No. 2463, which passed during the 1998 legislative session, amended and changed the code sections establishing the bed need formula that the Health Facilities Commission must follow when granting certificates of need for nursing home beds in Tennessee. During a fiscal year (July 1-June 30), the Commission shall issue no more than the designated number of Medicare skilled nursing facility beds for applicants filing for a certificate of need. The number of Medicare skilled nursing facility beds issued shall not exceed the allocated number of beds for each applicant. The applicant must also specify in the application the skilled services to be provided and how the applicant intends to provide such services.

A. Need

1. According to TCA 68-11-108, the need for nursing home beds shall be determined by applying the following population-based statistical methodology:

$$\begin{aligned}\text{County bed need} = & .0005 \times \text{pop. 65 and under, plus} \\ & .0120 \times \text{pop. 65-74, plus} \\ & .0600 \times \text{pop. 75-84, plus} \\ & .1500 \times \text{pop. 85, plus}\end{aligned}$$

2. The need for nursing home beds shall be projected two years into the future from the current year, as calculated by the Department of Health.
3. The source of the current supply and utilization of licensed and CON approved nursing home beds shall be the inventory of nursing home beds maintained by the Department of Health.
4. "Service Area" shall mean the county or counties represented on an application as the reasonable area to which a health care institution intends to provide services and/or in which the majority of its service recipients reside. A majority of the population of a service area for any nursing home should reside within 30 minutes travel time from that facility.
5. The Health Facilities Commission may consider approving new nursing home beds in excess of the need standard for a service area, but the following criteria must be considered:
 - a. All outstanding CON projects in the proposed service area resulting in a net increase in beds are licensed and in operation, and
 - b. All nursing homes that serve the same service area population as the applicant have an annualized occupancy in excess of 90%.

B. Occupancy and Size Standards:

1. A nursing home should maintain an average annual occupancy rate for all licensed beds of at least 90 percent after two years of operation.
2. There shall be no additional nursing home beds approved for a service area unless each existing facility with 50 beds or more has achieved an average annual occupancy rate of 95 percent. The circumstances of any nursing home, which has been identified by the Regional Administrator, as consistently noncomplying with quality assurance regulations shall be considered in determining the service areas, average occupancy rate.
3. A nursing home seeking approval to expand its bed capacity must have maintained an occupancy rate of 95 percent for the previous year.
4. A free-standing nursing home shall have a capacity of at least 30 beds in order to be approved. The Health Facilities Commission may make an exception to this standard. A facility of less than 30 beds may be located in a sparsely populated rural area where the population is not sufficient to justify a larger facility. Also, a project may be developed in conjunction with a retirement center where only a limited number of beds are needed for the residents of that retirement center.

SWING BED SERVICES

- A. Applicants must meet the same standards for determining need as applicants for nursing homes, with the exception of the standard for the minimum number of beds required for a freestanding nursing home.
- B. Applicants must meet appropriate federal criteria as mandated by the Health Care Financing Administration.
- C. Any existing provider must document that all deficiencies (if any) cited in the last licensure and/or certification inspection have been corrected.

ACUTE CARE BED NEED SERVICES

1. The following methodology should be used and the need for hospital beds should be projected four years into the future from the current year:

Using the latest utilization and patient origin data from the Joint Annual Report of Hospitals and the most current population projection series from the Department of Health, perform the following:

Step 1

Determine the current Average Daily Census (ADC) in each county.

$$\text{ADC} = \frac{\text{Patient Days}}{365 \text{ (366 in leap year)}}$$

Step 2

To determine the service area population (SAP) in both the current and projected year:

- a. Begin with a list of all the hospital discharges in the state, separated by county, and showing the discharges both by the county where the patient actually lives (resident discharges), and the county in which the patient received medical treatment.
- b. For the county in which the hospital is (or would be) located (service county), determine which other counties have patients who are treated in your county (resident counties). Treat all of the discharges from another state as if that whole state were a single resident county. The total discharges of residents from another state should be calculated from state population estimates and the latest National Center for Health Statistics southeastern discharge rates.
- c. For each resident county, determine what percent of their total resident discharges are discharged from a hospital in your service county (if less than one percent, disregard).
- d. For each resident county, apply the percentage determined above to the county's population (both projected and current). Add together the resulting numbers for all the resident counties and add that sum to the projected and current population of your service county. This will give you the service area population (SAP).

Step 3

Determine projected Average Daily Census as:

$$\text{Projected ADC} = \text{Current ADC} \times \frac{\text{Projected SAP}}{\text{Current SAP}}$$

Step 4

Calculate Projected Bed Need for each county as:

$$\text{Projected Need} = \text{Projected ADC} + 2.33 \times \text{Projected ADC}$$

However, if projected occupancy:

$$\text{Projected Occupancy} = \frac{\text{Projected ADC}}{\text{Projected Need}} \times 100$$

is greater than 80 percent, then calculate projected need:

$$\text{Projected Need} = \frac{\text{Projected ADC}}{.8}$$

2. New hospital beds can be approved in excess of the "need standard for a county" if the following criteria are met:
 - a) All existing hospitals in the projected service area have an occupancy level greater than or equal to 80 percent for the most recent Joint Annual Report. Occupancy should be based on the number of licensed beds that are staffed for two consecutive years.
 - b) All outstanding CON projects for new acute care beds in the proposed service area are licensed.
 - c) The Health Facilities Commission may give special consideration to acute care bed proposals for specialty health service units in tertiary care regional referral hospitals.

COMPREHENSIVE INPATIENT REHABILITATION SERVICES

1. The need for comprehensive inpatient rehabilitation beds shall be determined by applying the guideline of ten beds per 100,000 population in the service area of the proposal.
2. The need shall be based upon the current year's population and projected four years forward.
3. Applicants shall use a geographic service area appropriate to inpatient rehabilitation services.
4. Inpatient rehabilitation units in acute care hospitals shall have a minimum size of 8 beds.
5. Freestanding rehabilitation hospitals shall have a minimum size of 50 beds.
6. Additional inpatient rehabilitation beds, units, or freestanding hospitals should not be approved by the HFC unless all existing units or facilities are utilized at the following levels:

20-30 bed unit	~ 75%
31-50 bed unit/facility	~ 80%
51 bed plus unit/facility	~ 85%
7. The applicant must document the availability of adequate professional staff, as per licensing requirements, to deliver all designated services in the proposal. It is preferred that the medical director of a rehabilitation hospital be a board certified physiatrist.

AIR AMBULANCE SERVICES

1. The applicant must identify a specific service area and all existing providers of air ambulance services in the service area proposed.
2. The applicant must provide documentation of the aircraft selection and the reason for the selection of the particular aircraft.
3. A copy of the Federal Aviation Administration (FAA) Air Charter Certificate and documentation of the approved operations' specifications for air ambulance operations for the proposed aircraft must be provided.
4. The applicant must indicate the proposed number of air ambulance aircrafts by type and make and those currently in operation for the service area.
5. The applicant must project the number of estimated transports within the proposed service area and the estimated population and hospital facilities that will be served. Patient transport configuration must be indicated. Also, the number of scene flights and inter-facility transports for the proposed service area should be identified where possible.
6. The applicant must give a description of the proposed base or operations and the ability to provide air ambulance services on a 24 hour per day, seven-day per week basis, identifying the means to access and communicate with the air ambulance personnel on duty.
7. The applicant must provide documentation that identifies the qualifications, licensure, and credentials of the medical director and all patient care providers to assure compliance with Tennessee law and regulations pertaining to emergency medical services.
8. The applicant shall provide letters of commitment from any local government or emergency ambulance services to provide referrals or use for the planned air ambulance operations.
9. The impact of the proposal on existing services, and the basis for analysis should be assessed and considered. The applicant should provide a statement about the impact the proposed service is expected to have on any rotor-wing service within 75 miles.

NEONATAL NURSERY SERVICES

1. The total number of neonatal intensive and intermediate care beds should not exceed eight beds per 1,000 live births per year in a defined neonatal service area.
2. The need shall be based upon the current year's population projected four years forward.
3. A single neonatal special care unit shall contain a minimum of 15 beds. This is considered to be the minimum necessary to support economical operation of this service. An adjustment in the number of beds may be justified due to geographic remoteness.
4. The applicant shall designate a specific service area which is compatible with Department of Health guidelines pertaining to this service.
5. The applicant should demonstrate the ability to comply with the standards developed in the *Tennessee Perinatal Care System Guidelines for Regionalization, Hospital Care Levels, Staffing and Facilities*.
6. The target population shall have access to the proposed service in terms of payment for services, transportation, parking, geographical barriers, and access for the handicapped.
7. The Department of Health will consult with the Perinatal Advisory Committee regarding applications.

BURN UNITS

1. There should be no more than one burn unit bed for every 225,000 persons. This standard may be adjusted to reflect actual incidence in a geographic medical service area as documented by the applicant.
2. The need shall be based upon the current year's population projected four years forward.
3. Each new burn unit proposed shall have a minimum of 12 beds with 6-9 beds designated for adults and 3-6 beds for pediatric patients.
4. All existing specialized burn care beds in a service area must have an annual occupancy rate of 70 percent before any additional beds are approved.
5. Each proposed burn unit should document that a minimum of 50 patients with major burn injury to moderate uncomplicated burn injury will be treated each year.
6. Each burn unit shall have available, either through direct control or through a network of clearly identified relationships, a system of transportation sufficient to bring patients to the unit.
7. A network of relationships should be available to transport patients to other units when there are no beds available at a particular site.

DISCONTINUANCE OF OBSTETRICAL SERVICES

A. Need

1. A specific service area should be identified and all existing providers of obstetrical services in that service area should be identified.
2. The female population aged 15-44 in the service area should be identified. The current year's population and the population four years hence should be used.
3. The number of obstetrical patients served by the facility over the past three years should be listed.
4. The estimated number of obstetrical patients affected by the discontinuance of obstetrical services should be listed. The estimated number of obstetrical patients below the federally established poverty level and affected by the discontinuance of the service should be listed separately.

B. Accessibility

1. Indicate the distance in miles and approximate travel time that patients in need of obstetrical services would have to travel, should the service be discontinued at the designated site.
2. Indicate the modes of transportation which will be used by obstetrical patients to travel to alternate sites, should the service be discontinued at the designated site.
3. Indicate the facilities that will provide obstetrical services in the service area, should the service be discontinued at the designated site.
4. The charges for obstetrical services at alternate service delivery sites should be compared to those of the facility seeking to discontinue the service.
5. The applicant should document that TennCare and/or Medicare patients can receive obstetrical services at the alternate service delivery sites.

LONG TERM CARE HOSPITAL BEDS

A. Need

1. The need for long term care hospital (LTH) beds shall be determined by applying the guidelines of (0.5) beds per 10,000 population in the service area of the proposal.
2. If the project is a bed addition, existing long term care hospital beds must have a minimum average occupancy of 85%.
3. The population shall be the current year's population, projected two years forward.
4. The primary service area can not be smaller than the applicant's Community Service Area (CSA). If LTH beds are proposed within an existing hospital, CSAs served by the existing facility can be included along with consideration for populations in adjacent states when the applicant provides documentation (such as admission sources from the Joint Annual Report).
5. Long-term care hospitals should have a minimum size of 20 beds.

B. Economic Feasibility

1. The payer costs of a long-term hospital should demonstrate a substantial saving, or the services should provide additional benefit to the patient over the payer cost or over the provision of short-term general acute care alternatives, treating a similar patient mix of acuity.
2. The payer costs should be such that the facility will be financially accessible to a wide range of payers as well as to adolescent and adult patients of all ages.
3. Provisions will be made so that a minimum of 5% of the patient population using long-term acute care beds will be charity or indigent care.

C. Orderly Development

1. Services offered by the long term care hospital must be appropriate for medically complex patients who require daily physician intervention, 24 hours access per day of professional nursing (requiring approximately 6-8 hours per patient day of nursing and therapeutic services), and on-site support and access to appropriate multi-specialty medical consultants.

Patient services should be available as needed for the most appropriate provision of care. These services should include restorative inpatient medical care, hyperalimentation, care of ventilator dependent patients, long term antibiotic therapy,

long-term pain control, terminal AIDS care, and management of infectious and pulmonary diseases.

Also, to avoid unnecessary duplication, the project should not include services such as obstetrics, advanced emergency care, and other services which are not operationally pertinent to long term care hospitals.

2. The applicant should provide assurance that the facility's patient mix will exhibit an annual average aggregate length of stay greater than 25 days as calculated by the Health Care Finance Administration (HCFA), and will seek licensure only as a hospital.
3. The applicant should provide assurance that the projected caseload will require no more than three (3) hours per day of rehabilitation.
4. Because of the very limited statewide need for long term hospital beds, and their high overall acuity of care, these beds should be allocated only to community service areas and be either inside or in close proximity to tertiary referral hospitals, to enhance physical accessibility to the largest concentration of services, patients, and medical specialists.
5. In order to insure that the beds and the facility will be used for the purpose certified, any certificate of need for a long term care hospital should be conditioned on the institution being certified by the Health Care Financing Administration as a long term care hospital, and qualifying as PPS-exempt under applicable federal guidelines. If such certification is received prior to the expiration date of the certificate of need, as provided in Tennessee Code Annotated (TCA), Section 68-11-108(c), the certificate of need shall expire, and become null and void.

CONSTRUCTION, RENOVATION, EXPANSION, AND REPLACEMENT OF HEALTH CARE INSTITUTIONS

1. Any project that includes the addition of beds, services, or medical equipment will be reviewed under the standards for those specific activities.
2. For relocation or replacement of an existing licensed health care institution:
 - a. The applicant should provide plans which include costs for both renovation and relocation, demonstrating the strengths and weaknesses of each alternative.
 - b. The applicant should demonstrate that there is an acceptable existing or projected future demand for the proposed project.
3. For renovation or expansions of an existing licensed health care institution:
 - a. The applicant should demonstrate that there is an acceptable existing demand for the proposed project.
 - b. The applicant should demonstrate that the existing physical plant's condition warrants major renovation or expansion.

SECTION II

MENTAL HEALTH, MENTAL RETARDATION, AND ALCOHOL AND DRUG ABUSE SERVICES

PSYCHIATRIC INPATIENT SERVICES

A. Need

1. The population-based estimate of the total need for psychiatric inpatient services is 30 beds per 100,000 general population (using population estimates prepared by the Department of Health and applying the data in Joint Annual Reports).
2. For adult programs, the age group of 18 years and older should be used in calculating the estimated total number of beds needed.
3. For child inpatient under age 13, and if adolescent program the age group of 13-17 should be used.
4. These estimates for total need should be adjusted by the existent staffed beds operating in the area as counted by the Department of Health in the Joint Annual Report.

B. Service Area

1. The geographic service area should be reasonable and based on an optimal balance between population density and service proximity or the Community Service Agency.
2. The relationship of the socio-demographics of the service area, and the projected population to receive services, should be considered. The proposal's sensitivity to and responsiveness to the special needs of the service area should be considered including accessibility to consumers, particularly women, racial and ethnic minorities, low income groups, and those needing services involuntarily.

C. Relationship to Existing Applicable Plans

1. The proposal's relationship to policy as formulated in state, city, county, and/or regional plans and other documents should be a significant consideration.
2. The proposal's relationship to underserved geographic areas and underserved population groups as identified in state, city, county and/or regional plans and other documents should be a significant consideration.
3. The impact of the proposal on similar services supported by state appropriations should be assessed and considered.
4. The proposal's relationship to whether or not the facility takes voluntary and/or involuntary admissions, and whether the facility serves acute and/or long-term patients, should be assessed and considered.
5. The degree of projected financial participation in the Medicare and TennCare programs should be considered.

D. Relationship to Existing Similar Services in the Area

1. The area's trends in occupancy and utilization of similar services should be considered.
2. Accessibility to specific special need groups should be an important factor.

E. Feasibility

The ability of the applicant to meet Tennessee Department of Mental Health licensure requirements (related to personnel and staffing for psychiatric inpatient facilities) should be considered.

ICF/MR FACILITIES

A. Need

1. The population-based estimate of the total need for ICF/MR facilities is .032 percent of the general population. This estimate is based on the estimate for all mental retardation of 1 percent. Of the 1 percent estimate, 3.2 percent of those are estimated to meet level 1 criteria and be appropriate for ICF-MR services.
2. The estimate for total need should be adjusted by the existent ICF-MR beds operating in the area as counted by the Department of Health, the Department of Mental Health and Developmental Disabilities, and the Division of Mental Retardation Services in the Joint Annual Reports.

B. Service Area

1. The geographic service area should be reasonable and based on an optimal balance between population density and service proximity.
2. The relationship of the socio-demographics of the service area and the project population to receive services should be considered. The proposal's sensitivity and responsiveness to the special needs of the service area should be considered including accessibility to consumers, particularly women, racial and ethnic minorities, low-income groups, and those needing services involuntarily.

C. Relationship to Existing Applicable Plans

1. The proposal's relationship to policy as formulated in state, city, county, and/or regional plans and other documents should be a significant consideration.
2. The proposal's relationship to underserved geographic areas and underserved populations groups as identified in state, city, county, and/or regional plans and other documents should be a significant consideration.
3. The impact of the proposal on similar services supported by state and federal appropriations should be assessed and considered.
4. The degree of projected financial participation in the Medicare and TennCare programs should be considered.

D. Relationship to Existing Similar Services in the Area

1. The area's trends in occupancy and utilization of similar services should be considered.
2. Accessibility to specific special need groups should be an important factor.

MENTAL HEALTH RESIDENTIAL TREATMENT FACILITIES

A. Need

1. The population-based estimate of the total need for adult residential treatment facilities is 20 beds per 100,000 general population.
2. For children and adolescents, the methodology of the Pires CASSP Model should be followed. See Methodology: *State of Tennessee Department of Children's Services Plan*.
3. For adult facilities, the age group of 18 years and older should be used in calculating the estimated total number of beds needed.
4. For child and adolescent facilities, the age group under 18 should be used.
5. These estimates for total need should be adjusted by the existent residential beds operating in the service area.

B. Service Area

1. The geographic service area should be reasonable and based on an optimal balance between population density and service proximity, or the Community Service Agency.
2. The relationship of the socio-demographics of the service area and the projected population to receive services should be considered. The proposal's sensitivity to and responsiveness to the special needs of the service area should be considered including accessibility to consumers, particularly women, racial and ethnic minorities, low-income consumers, and consumers with dual diagnosis.

C. Relationship to Existing Applicable Plan

1. The proposal's relationship to policy as formulated in local plans, the *Department of Children's Services Plan*, and the *Department of Mental Health's Master Plan* should be a significant consideration.
2. The proposal's relationship to underserved geographic areas and underserved population groups as identified in state, city, county, and regional plans and the *Department of Children's Services Plan*, and the *Department of Mental Health's Master Plan* should be a significant consideration.
3. The impact of the proposal on similar services supported by state appropriations should be assessed and considered.

D. Relationship to Existing Similar Services in the area;

1. The area's trends in occupancy and utilization of similar services should be considered.
2. Accessibility to specific special need groups should be an important factor.

E. Feasibility

The ability of the applicant to meet Tennessee Department of Mental Health and Developmental Disabilities licensure requirements, related to personnel and staffing for residential treatment facilities, should be considered.

METHODOLOGY

The general steps required in the Pires CASSP model applied to the 12 Community Service Agency (CSA) regions are listed below:

1. Estimate the total number of children in the target population in the State.
2. Estimate the total number of children in each CSA region.
3. Estimate the percentage of children in need of each type of service using:
 - a. National estimates of need
 - b. Estimates of need in other Tennessee studies
 - c. Evaluation of historic State and regional utilization rates
 - d. Adjustments for instability factors (e.g., divorce, poverty, etc.)
4. Multiply the percentage of children in need from #3 times the total number of children from #1 or #2 to estimate the children in need of each type of service by each CSA region.
5. State the desired length of stay or length of service for each service type for each CSA region.
6. To calculate the total number of client days for each type of service in each CSA region, divide the number of children in need by the preferred length of stay.
7. To calculate the Average Daily Census for each type of service in each CSA region, divide the total number of client days by the daily availability of services (e.g. 365).
8. To calculate the total number of slots/beds available for each type of service in each CSA region, divide the Average Daily Census by the desired occupancy rates.

ALCOHOL AND DRUG ABUSE RESIDENTIAL TREATMENT FACILITIES

A. Need

1. The population-based estimate of the total need for alcohol and drug residential treatment facilities will be based on information from a community needs assessment for the proposed service area, including present licensed alcohol and drug residential treatment bed capacity and utilization of present capacity of all existing licensed alcohol and drug residential treatment beds. This need applies only to programs with a length of stay of 29 days or longer. It applies to child and adolescent programs in hospitals.
2. For child and adolescent alcohol and drug residential treatment programs, the age group of 13-17 should be used.
3. These estimates for total need should be adjusted by the licensed existent alcohol and drug residential treatment beds operating in the specified area, as counted by the Department of Health in the Joint Annual Report.

B. Service Area

1. The geographic service area should be reasonable and based on an optimal balance between population density and alcohol and drug licensed residential treatment service proximity.
2. The relationship of the socio-demographics of the service area and the projected population to receive alcohol and drug residential treatment services should be considered. The proposal's sensitivity to and responsiveness to the special needs of the service area should be considered including accessibility to consumers, particularly women, racial and ethnic minorities, low-income groups, and those needing services involuntarily.

C. Relationship to Existing Applicable Plans

1. The proposal's relationship to policy as formulated in local governmental health plans and other documents should be a significant consideration.
2. The proposal's relationship to underserved geographic areas and underserved populations groups, as identified in local plans and other documents, should be a significant consideration.
3. The impact of the proposal on similar services supported by state appropriations should be assessed and considered.
4. The degree of projected financial participation in the Medicare and TennCare programs should be considered.

D. Relationship to Existing Similar Services in the Area

1. The area's trends in occupancy and utilization of similar services should be considered.
2. Accessibility to specific special need groups should be an important factor.

NON-RESIDENTIAL METHADONE TREATMENT FACILITIES (NRMTF)

A non-residential narcotic treatment facility should provide adequate medical, counseling, vocational, educational, mental health assessment, and social services to patients enrolled in the opioid treatment program with the goal of the individual becoming free of opioid dependency.

Need

The need for non-residential narcotic treatment facilities should be based on information prepared by the applicant for a certificate of need which acknowledges the importance of considering the demand for services along with need and addressing and analyzing service problems as well.

The assessment should cover the proposed service area and include the utilization of existing service providers, scope of services provided, patient origin, and patient mix.

The assessment should consider that the users of opiate drugs are the clients at non-residential narcotic treatment facilities, and because of the illegal nature of opiate drug use, data will be based on estimates, actual counts, arrests for drug use, and hospital admittance for drug abuse.

The assessment should also include:

1. A description of the geographic area to be served by the program;
2. Population of area to be served;
3. The estimated number of persons, in the described area, addicted to heroin or other opioid drugs and an explanation of the basis of the estimate;
4. The estimated number of persons, in the described area, addicted to heroin or other opioid drugs presently under treatment in methadone and other treatment programs;
5. Projected rate of intake and factors controlling intake;
6. Compare estimated need to existing capacity.

Also, consideration should be given to the reality that existing facilities can expand or reduce their capacity to maintain or treat patients without large changes in overhead.

Service Area

The geographic service area should be reasonable and based on an optimal balance between population density and service proximity.

The relationship of the socio-demographics of the service area and the projected population to receive services should be considered. The proposal's sensitivity to and the responsiveness to the special needs of the service area should be considered including accessibility to consumers, particularly women, racial and ethnic minorities, and low-income groups.

Relationship to Existing Applicable Plans

The proposals' estimate of the number of patients to be treated, anticipated revenue from the proposed project, and the program funding source with description of the organizational structure of the program delineating the person(s) responsible for the program, should be considered.

The proposals' relationship to policy as formulated in local and national plans, including need methodologies, should be considered.

The proposals' relationship to underserved geographic areas and underserved population groups, as identified in local plans and other documents, should be a significant consideration.

The impact of the proposal on similar services supported by state appropriations should be assessed and considered.

The degree of projected financial participation in the Medicare and TennCare programs should be considered.

SECTION III

MEDICAL EQUIPMENT AND SERVICES

EXTRA-CORPOREAL SHOCK WAVE LITHOTRIPSY

A. Need

1. The need for extra-corporeal shock wave lithotripsy (ESWL) services should be determined by using the following population-based methodology: $\text{ESWL Need} = 1 \text{ ESWL Unit} / 250,000 \text{ Population}$.
2. The need shall be based upon the current year's population projected four years forward.
3. Applicants must identify the specific geographical area around the service site.
4. Only equipment which has been approved by the United States Food and Drug Administration (FDA) for clinical use shall be approvable.
5. Applicants proposing to acquire and operate a ESWL unit must project a minimum utilization of at least 250 procedures per year by the third year of operation. The applicant must also document and provide data supporting the methodology used to project the patient utilization.

B. The availability of adequate health manpower and management personnel should be documented through the use of the following guidelines:

1. Applicants must have sufficient staff and a full range of professional and para-professional personnel for efficient operation and must document the following:
 - a. An active radiology service and an established referral urological practice;
 - b. The availability and proximity of acute inpatient services for patients who experience complication; and
 - c. All individuals using the equipment meet the training and credentialing requirements of the American Lithotripsy Society.
2. Applicants must document an acceptable plan for the development of transfer and/or affiliation agreements with other hospitals in the service area (this does not preclude the development of agreements with facilities outside the applicant's service area).
3. Applicants must document that the governing body of the entity providing ESWL services will grant an appropriate scope of privileges for access to the lithotripter to any qualified physician who makes application for privileges.
4. The applicant shall agree in writing to provide the Health Facilities Commission actual data on the operation of the ESWL service and summaries.

POSITRON EMISSION TOMOGRAPHY (PET)

Go to “State Health Plan,” Appendix A, Page 117 [by copying and pasting the following link:
<http://www.tn.gov/finance/healthplanning/Documents/2009TennesseeStateHealthPlan.pdf>]

5. The HFC may consider the special needs of major regional tertiary care facilities in determining the need for ESWL services.
6. The HFC may consider the special needs of rural areas in determining the needs for ESWL services, particularly in the case of mobile units.

MAGNETIC RESONANCE IMAGING (MRI)

1. The applicant shall demonstrate that the geographical area comprising the proposed service area has a population and a medical community sufficient to utilize the magnetic resonance imaging device at a rate of 2,200 MRI procedures per year.
2. Approval of additional MRI services will be made only when it is demonstrated that the existing MRI services in the applicant's geographical service area are performing an average of at least 2,200 clinical procedures per MRI unit per year.
3. The applicant must provide evidence that the proposed MRI equipment is safe and effective for its proposed use:
 - a. The United States Food and Drug Administration (FDA) shall certify the proposed equipment for clinical use.
 - b. The applicant must demonstrate the proposed MRI's services will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.
 - c. The applicant must demonstrate how emergencies within the MRI facility will be managed in conformity with accepted medical practice.
 - d. The applicant must establish protocols that assure that all clinical MRI procedures performed are medically necessary and will not unnecessarily duplicate other services.
 - e. The applicant must provide supervision and interpretation by a board certified radiologist or physician demonstrating experience and training in the relevant imaging procedure, with certification by the appropriate regulatory body.
4. An exception to the standard number of procedures may occur as new or improved technology and equipment or new diagnostic applications for this type of service are developed. The applicant must demonstrate that the proposed unit offers a unique and necessary technology for the provision of health services in the geographical service area.
5. Mobile units would not be subject to the need standard in #1 above if fewer than 150 days of service per year are provided at a given location. However, the applicant must demonstrate that existing services in the applicant's geographical area are not adequate and/or there are special circumstances that require additional services.
6. The acquisition of an additional MRI scanner at an existing MRI facility is not considered an upgrade to services. A CON application for provision of additional MRI services is required in such cases.

MEGAVOLTAGE RADIATION THERAPY SERVICE

1. The need for megavoltage radiation therapy equipment shall be based upon the following assumptions:

- a. Each radiation therapy unit should serve a population base of at least 120,000 people.
- b. Minimum capacity is 6,000 procedures per unit annually serving a minimum of 300 cancer patients annually.
- c. Optimal capacity is 9,984 procedures per unit annually.

(Capacity is determined by assuming that 4 patients per hour x 48 hours per week x 52 weeks per year equals 9,984. The minimum capacity assumes 60% utilization of each piece of equipment. The net operational hours include allowances for equipment quality assurance procedures, warm-up time for a linear accelerator, room preparation, and other support activities.)

2. The need should be based upon the current year's population projected four years into the future.
3. The service area shall mean the county or counties represented by an applicant as the reasonable area to which a health care institution intends to provide radiation therapy services and/or in which the majority of its service recipients reside.
4. No additional megavoltage radiation therapy units shall be approved unless every existing unit in the service area has performed 6,000 or more procedures per unit annually.
5. The applicant must provide evidence that the proposed radiation therapy equipment is safe and effective for its proposed use:
 - a. The United States Food and Drug Administration (FDA) shall certify the proposed equipment for clinical use.
 - b. The applicant must demonstrate the proposed service will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and all licensing agencies' requirements.
 - c. Staffing should include a radiation oncologist, a radiation physicist, and two therapy technologists per unit.

SECTION IV

HOME HEALTH AND HOSPICE SERVICES

HOME HEALTH SERVICES

1. The need for home health agencies/services shall be determined on a county by county basis.
2. In a given county, 1.5 percent of the total population will be considered as the need estimate for home health services in that county.

The 1.5 percent formula will be applied as a general guideline, as a means of comparison within the proposed service area.

3. Using recognized population sources, projections for four years into the future will be used.
4. The use rate of existing home health agencies in the county will be determined by examining the latest utilization rate as calculated in the Joint Annual Report of existing home health agencies in the service area.

Based on the number of patients served by home health agencies in the service area, an estimation will be made as to how many patients could be served in the future.

5. Documentation from referral sources:

- a. The applicant shall provide letters of intent from physicians and other referral sources pertaining to patient referral.
- b. The applicant shall provide information indicating the types of cases physicians would refer to the proposed home health agency and the projected number of cases by service category to be provided in the initial year of operation.
- c. The applicant shall provide letters from potential patients or providers in the proposed service area that state they have attempted to find appropriate home health services but have not been able to secure such services.
- d. The applicant shall provide information concerning whether a proposed agency would provide services different from those services offered by existing agencies.

6. The proposed charges shall be reasonable in comparison with those of other similar facilities in the service area or in adjoining service areas.

- a. The average cost per visit by service category shall be listed.
- b. The average cost per patient based upon the projected number of visits per patient shall be listed.

RESIDENTIAL HOSPICE SERVICES

1. The need for residential hospice services shall be determined by using the Residential Hospice Bed Need Formula (see page 42).
2. The "service area" shall mean the county or counties represented on an application as the reasonable area to which a health care institution intends to provide services and/or in which the majority of its service recipients reside.
3. The services of other residential hospices in the county or the service area will be taken into consideration.
4. The determination of hospice service areas should take into account several factors. These factors include but are not limited to:
 - a. the size of the population required to support the hospice program;
 - b. the size of the geographic area;
 - c. the distance that families might be reasonably expected to travel to visit members of their family; and
 - d. the existing health care resources and coordinating mechanisms that exist which might be expected to assist the residential hospice.
5. The purpose of establishing residential hospice facilities is not to replace home care hospice purposes, but rather to provide an option to those patients who cannot be adequately cared for in the home setting. The reasons for this may vary, but include people who have no available able or willing caregiver or people who reside in inadequate living environments.
6. The applicant must demonstrate an ability and willingness to serve equally all of the geographic area in which it seeks certification.
7. The applicant should provide a plan for how it intends to educate physicians, hospital discharge planners, and public health nursing agencies about the need for timely referral of potential hospice patients.
8. The delivery of prescribed services should not be limited by the patient's payment mechanism.
9. The sponsor's case mix shall be reasonably consistent with that of existing hospices in the service area and should not exclude hard-to-serve patients.
10. The applicant should demonstrate a willingness to work with other community-based organizations to develop informal support systems to enable homeless persons and those without a primary care system to benefit from hospice services.

11. At least the following data should be collected on an ongoing basis for accountability in program planning and monitoring budgetary priorities:

- ~ total number of clients seen annually;
- ~ number of clients by age, sex, race, diagnosis, discipline;
- ~ number of clients by source of referral;
- ~ average length of stay;
- ~ average daily census;
- ~ indicate the diagnosis for each patient, i.e., cancer, AIDS, etc.;
- ~ total days of respite care and inpatient care;
- ~ site of death for all patients who die in the program;
- ~ average annual cost per patient per year.

Tennessee Residential Hospice Bed Need Formula

Cancer death statistics to be used are from the most recent year.

Number of cancer deaths in this county "example" is 1,000.

- A. Cancer patients utilizing hospice services is assumed to be 40% x cancer death cases (1,000) in the county.

$$40\% \times 1,000 = 400$$

- B. Other hospice users is assumed to be 15% of the estimated cancer patients (400) utilizing the hospice service.

$$400 \times 15\% = 60$$

- C. Total hospice users = (A) cancer patients utilizing hospice services and (B) other (non-cancer) hospice patients utilizing hospice services.

$$A + B = \text{Total number of hospice patients.}$$

$$400 + 60 = 460$$

- D. Total number of hospice patients (460) times the average length of stay x (45 days) – the uniform state standard for all counties = total hospice days.

$$460 \times 45 = 20,700$$

- E. Total hospice days 20,700, divided by 365 days =

$$\frac{20,700}{365} = 57 \text{ Average Daily Hospice Census}$$

- F. Inpatient bed need is 20% of the average daily hospice census (E) divided by the expected occupancy rate, which is .85.

$$20\% \times 57 = 11$$

$$11 \times .85 = 13 \text{ residential hospice beds}$$

Footnotes

1. All figures are rounded off to whole numbers.
2. The Tennessee formula utilizes the format of the New York State Residential Hospice Bed Need Formula. However, the components of the Tennessee formula are based on health statistics and/or health trends pertinent to the State of Tennessee. Statistics to be used in this formula will be obtained from the Tennessee Department of Health.
3. Forty-five (45) days are the uniform state standard used for average length of stays and will be applied to all counties.

HOSPICE SERVICES

Need

1. Hospices shall have the capacity to admit new patients in a quantity equal to the sum of:
 - a. 55% of the mean annual number of cancer deaths in the hospice service area during the preceding two years; and
 - b. 12% of the mean annual number of deaths from all other non-traumatic causes in the hospice service area during the preceding three years.
2. New hospices shall be approved for Certificate of Need only if the projected need, as determined by this formula, exceeds existing service levels by 150 or more patients per year.

CON Review Criteria

1. The application shall document the existence of at least one of the following three conditions to demonstrate a need for additional hospice services in an area:
 - a. absence of services by a hospice certified for Medicaid and Medicare, and evidence that the applicant will provide Medicaid- and Medicare-certified hospice in the area; or
 - b. absence of services by a hospice that serves patients regardless of the patient's ability to pay, and evidence that the applicant will provide services for patients regardless of ability to pay; or
 - c. evidence that existing programs fail to meet the demand for hospice services for persons who have terminal cancer or other qualifying terminal illness.
2. The applicant shall set forth its plan for care of patients without private insurance coverage and its plan for care of medically underserved populations. The applicant shall include demographic identification of underserved populations in the applicant's proposed service area and shall not deny services solely based on the patient's ability to pay.

Exception to the Hospice Formula

The applicant must demonstrate that circumstances exist to justify the approval of a new hospice. Evidence submitted by the applicant must document one or more of the following:

1. That a specific terminally ill population is not being served;
2. That a county or counties within the service area of a licensed hospice program are not being served; and
3. That there are persons referred to hospice programs who are not being admitted within 48 hours (excluding cases where a later admission date has been requested). The applicant shall indicate the number of persons.

If the need for the exception to the hospice formula is justified, then the review criteria above shall also apply.

SECTION V

SPECIAL PROCEDURES

OPEN HEART SURGERY SERVICES

1. The need for open heart surgery services is determined by applying the following formula. The formula serves to derive the number of open heart procedures which may be needed in a particular service area.

$$N = U \times P$$

where: N = number of procedures in a service area;

U = latest available Tennessee use rate (number of procedures performed per 1,000 population in the state); and

P = projection of population (in thousands) in the service area.

2. The need for open heart surgery services shall be projected four years into the future from the current year.
3. The service area shall mean the county or counties represented by an applicant as the reasonable area to which a health care institution intends to provide open heart surgery services, and in which the majority of its service recipients reside.
4. Adult open heart surgery programs shall perform at least 200 operations per year within three years of initiation and each year thereafter. The pediatric standard is 100.
5. No new adult open heart surgery programs may be established unless the number of open heart operations performed per year by each existing and approved program in the proposed service area of proposed facility exceeds 350. The pediatric standard is 130.
6. No new open heart surgery programs shall be approved if the new program will cause the annual caseload of other programs within the service area to drop below 350 adult procedures or 130 pediatric procedures.
7. Consider the accessibility of medical services by the population to be served.
 - a. The maximum travel time to hospitals providing open heart surgery services should be within a maximum one-way driving time of two hours for at least 90 percent of the population.
 - b. Elective open heart surgery services should be available within two weeks from the date of the patient's decision to undergo surgery.

CARDIAC CATHETERIZATION SERVICES

Go to “State Health Plan,” Appendix B, Page 120 [by copying and pasting the following link:
<http://www.tn.gov/finance/healthplanning/Documents/2009TennesseeStateHealthPlan.pdf>]

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SECTION VI

TREATMENT AND DIAGNOSTIC CENTERS

AMBULATORY SURGICAL TREATMENT CENTERS

1. The need for an ambulatory surgical treatment center shall be based upon the following assumptions:
 - a. An operating room is available 250 days per year, 8 hours per day.
 - b. The average time per outpatient surgery case is 60 minutes.
 - c. The average time for clean up and preparation between outpatient surgery cases is 30 minutes.
 - d. The capacity of a dedicated, outpatient, general-purpose operating room is 80% of full capacity. That equates to 800 cases per year.
 - e. Unstaffed operating rooms are considered available for ambulatory surgery and are to be included in the inventory and in the measure of capacity.
2. "Service Area" shall mean the county or counties represented by the applicant as the reasonable area to which the facility intends to provide services and/or in which the majority of its service recipients reside.
3. The majority of the population of a service area for an ambulatory surgical treatment center should reside within 30 minutes travel time to the facility.
4. All applicants should demonstrate the ability to perform a minimum of 800 operations and/or procedures per year per operating room and/or procedure room. This assumes 250 days x 4 surgeries/procedures x .80.
5. A certificate of need (CON) proposal to establish a new ambulatory surgical treatment center or to expand the existing services of an ambulatory surgical treatment center shall not be approved unless the existing ambulatory surgical services within the applicant's service area or within the applicant's facility are demonstrated to be currently utilized at 80% of service capacity. Notwithstanding the 80% need standard, the Health Facilities Commission may consider proposals for additional facilities or expanded services within an existing facility under the following conditions: proposals for facilities offering limited-specialty type programs or proposals for facilities where accessibility to surgical services is limited.
6. A CON proposal to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment must specify the number of projected surgical operating rooms to be designated for ambulatory surgical services.
7. A CON proposal to establish an ambulatory surgical treatment center or to expand existing services of an ambulatory surgical treatment center must project patient utilization for each of the first eight quarters following the completion of the proposed project. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

8. A CON proposal to establish an ambulatory surgical treatment center or to expand the existing services of an ambulatory surgical treatment center must project patient origin by percentage and county of residence. All assumptions, including the specific methodology by which utilization is projected, must be clearly stated.

OUTPATIENT DIAGNOSTIC CENTERS

1. The need for outpatient diagnostic services shall be determined on a county by county basis (with data presented for contiguous counties for comparative purposes) and should be projected four years into the future using available population figures.
2. Approval of additional outpatient diagnostic services will be made only when it is demonstrated that existing services in the applicant's geographical service area are not adequate and/or there are special circumstances that require additional services.
3. Any special needs and circumstances:
 - a. The needs of both medical and outpatient diagnostic facilities and services must be analyzed.
 - b. Other special needs and circumstances, which might be pertinent, must be analyzed.
 - c. The applicant must provide evidence that the proposed diagnostic outpatient services will meet the needs of the potential clientele to be served.
 1. The applicant must demonstrate how emergencies within the outpatient diagnostic facility will be managed in conformity with accepted medical practice.
 2. The applicant must establish protocols that will assure that all clinical procedures performed are medically necessary and will not unnecessarily duplicate other services.

BIRTHING CENTERS

1. The approval of a birthing center will be made only when it is demonstrated that the accessibility to adequate obstetrical and gynecological services in the applicant's geographical service area are limited and/or there are special circumstances which require additional services.
2. A specific service area should be identified and all existing providers of obstetrical services in that service area should be identified. Service area shall mean the county or counties represented by the applicant as the reasonable area to which the facility intends to provide services and/or in which the majority of the service recipients reside. The service area should be based on an optimal balance between population density and service proximity.
3. The female population aged 15-44 in the service area should be identified. The current year's population and the population four years hence should be used.
4. The relationship of the socio-demographics of the service area and the projected population to receive services should be considered. The proposal's sensitivity to and responsiveness to the special needs of the service area should be considered, including the accessibility to consumers, particularly women, racial and ethnic minorities, and low-income consumers.
5. The applicant must identify the existing facilities providing obstetrical services in the service area and their utilization.
6. The applicant must indicate the distance and approximate travel time that patients in need of emergency obstetrical services would have to travel to the nearest acute care facility to receive emergency care.
7. The applicant must indicate the modes of transportation that will be used by obstetrical patients for emergency transfer. The applicant must have written protocols, procedures, and transfer agreements for the appropriate transfer of patients to a nearby acute care facility offering obstetrical services for emergency care.
8. The charges for obstetrical services for the proposed facility should be indicated and compared to those of existing obstetrical service providers in the proposed service area.
9. The applicant must document the availability of adequate professional staff to provide services 24 hours a day, seven days a week, as per licensing requirements; to deliver all designated obstetrical services in the proposal. The governing body of the birthing center must appoint a medical director who is board certified in obstetrics/gynecology or family practice. Each physician practicing or consulting in the birthing center shall have admitting privileges at a designated back-up hospital.
10. The applicant must demonstrate that the proposed obstetrical services will be offered in a physical environment that conforms to applicable federal standards, manufacturer's specifications, and licensing agencies' requirements.